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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,148	11/17/2003	Michael D. Seidman	MDS-10202/03	4310

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GIFFORD, KRASS, GROH, SPRINKLE & CITKOWSKI, P.C
PO BOX 7021
TROY, MI 48007-7021

EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/715,148	SEIDMAN, MICHAEL D.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-9,11,12,14,15 and 17-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-9,11,12,14,15 and 17-21* is/are rejected.

7)☒ Claim(s) *11 and 20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-2, 4-9, 11-12, 14-15 and 17-21 are presented for examination.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 18, 2006 has been entered. Accordingly, the specification at pages 3, 8 and 22 has been amended and claims 1, 11 and 20 have been amended.

In view of the amendments and remarks made herein, the objection to claim 1 for failing to consistently refer to "+/- alpha-lipoic acid" as such; the objection to claims 11 and 20 for clarity; and the objections to the specification as set forth at pages 2-3 of the previous Office Action dated July 18, 2005 have each been hereby **withdrawn**.

Objection to the Claims

Insofar as Applicant failed to address the inconsistent reference to "+/- alpha-lipoic acid" in present claims 11 and 20 as set forth in the objection to the claims at pages 2-3 of the previous Office Action dated July 18, 2005, the objection to claims 11 and 20 remains proper and is repeated below.

Claims 11 and 20 remain objected to for failing to consistently refer to "+/- alpha-lipoic acid" as such. See particularly line 7 of claim 11 and line 9 of claim 20. Applicant may wish to consider amending the claims in the following manner in order to obviate the objection. Claim

11 is provided below as an example. Should Applicant adopt such a suggestion, claim 20 should be amended in a manner consistent with the suggestion below.

---11. (Currently Amended) A nutritional supplement comprising at least two components administered in effective daily dosages selected from the group consisting of:

50-1000 mg +/- alpha-lipoic acid,

100-5000 mg acetyl-L-carnitine,

45-1000 mg resveratrol;

200-2000 mg lecithin; and

100-2500 mg N-acetyl cysteine with the proviso that the +/- alpha-lipoic acid and the acetyl-L-carnitine are not administered together.---

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 4-9, 11-12, 14-15 and 17-21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Chopra (U.S. Patent No. 6,300,377; 2001) in view of Stedman's Medical Dictionary (1972; page 1243), Garrett and Grisham's *Biochemistry* (1999; pages 244-247), The Merck Index (1992; Monograph 9255) and Drug Facts and Comparisons (1996; ages 1064-1070), each already of record, for the reasons made of record as set forth at pages 3-5 of the

previous Office Action dated July 18, 2005 and at pages 4-11 of the previous Office Action dated March 29, 2005.

Applicant states that Chopra does not render obvious all possible combinations wherein alpha-lipoic acid and acetyl-L-carnitine are not administered in the same supplement and that Chopra would not suggest to one of ordinary skill in the art that there was particular therapeutic advantage in avoiding the administration of alpha-lipoic acid and acetyl-L-carnitine together. Applicant further submits that Examiner has expressed the idea that no invention can lie in the choice of a particular optimum dosage to promote cognitive or auditory function and there is no basis for deeming the specific dosages set forth in the present claims to be obvious in view of the cited references.

Applicant's amendments and remarks have each been carefully considered in their entirety, but fail to be persuasive in establishing error in the propriety of the present rejection.

While it is noted that Applicant may have discovered a previously unknown advantage when concomitant administration of alpha-lipoic acid and acetyl-L-carnitine is avoided, the very teaching of "or mixtures thereof" of the disclosed active agents of N-acetyl cysteine, alpha-lipoic acid (thioctic acid), acetyl-L-carnitine and resveratrol expressly provides for all possible combinations of at least two of the bioactive agents listed above. Such a statement explicitly provides for situations wherein alpha-lipoic acid and acetyl-L-carnitine are **not** administered in the same supplement. Consideration of the size of the genus of bioactive agents (i.e., only 4 agents; N-acetyl cysteine, alpha-lipoic acid (thioctic acid), acetyl-L-carnitine and resveratrol) would have necessarily lead the skilled artisan to immediately envisage combinations of at least

two of these bioactive agents wherein alpha-lipoic acid and acetyl-L-carnitine are not administered in the same supplement.

Furthermore, the assertion that Chopra would not render obvious all possible combinations of alpha-lipoic acid and acetyl-L-carnitine are not administered in the same supplement has not been supported by any sound scientific reasoning or evidence as to why such would not have been obvious to one of ordinary skill in the art since the teachings of Chopra and the other cited references teach to the contrary (i.e., that it would have been *prima* obvious). Therefore, such an argument amounts to no more than a general allegation of counsel and, in the absence of any supporting evidence or reasoning, is not at all found to be persuasive.

Moreover, the argument that Chopra would not suggest to one of ordinary skill in the art that there existed a therapeutic advantage in avoiding the administration of such two agents together has been carefully considered, but is also not found persuasive because the reference expressly provides for such a situation and that very fact is considered to be sufficient suggestion to the skilled artisan.

Should Applicant be intending to claim an unexpected result or advantage, Applicant would need to provide adequate evidence and reasoning to that effect. The mere assertion of an unexpected advantage is not sufficient to establish patentable distinction over the cited references.

While Applicant's remarks concerning the presently claimed dosage amounts have been carefully considered, they are also not found to be persuasive. Applicant states that, "the Examiner is expressing the concept that no invention can lie in the choice of a particular optimum dosage reference to promote cognitive or auditory function". Such a statement is a

mischaracterization of the Examiner's remarks. Nowhere in the rejection does it state that there does not exist any inventive concept in determining an optimum dosage range that provides unexpectedly superior results.

However, it is noted that the determination of a particular dosage regimen is, absent factual evidence to the contrary, a skill that was well within the purview of the skilled artisan at the time of the invention using knowledge that was generally available to one of ordinary skill in the art. In other words, such a determination would have been *prima facie* obvious to the skilled artisan, in the absence of any evidence or direction to the contrary.

Applicant's attention is drawn to MPEP at §2144.05, which states, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages...Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." Although the present claims are drawn to milligram dosage amounts, such a motivation is nonetheless relevant.

Once again, it is noted that should Applicant have been the first to discover that a particular dosage amount of the claimed active components results in an unexpected advantage in the promotion of cognitive or auditory function over what would have been generally expected by one of ordinary skill in the art, Applicant would need to provide adequate evidence and reasoning to that effect. The mere assertion of an unexpected advantage is, again, not sufficient to establish patentable distinction over the cited references.

Conclusion

Rejection of claims 1-2, 4-9, 11-12, 14-15 and 17-21 is deemed proper and is **maintained**.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie A. Royds
Patent Examiner
Art Unit 1614

February 2, 2006

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600